



DEC 21 2005

B. Aaron Schulman
LARSON & TAYLOR PLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA VA 22314-1437In Re: Patent Term Extension
Application for
U.S. Patent No. 4,839,350

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,839,350, which claims the human drug product SPECTRACEF®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,036 days. U.S. Patent No. 4,839,350 has an original expiration date of June 13, 2006, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,036 days will result in an extended expiration date of April 14, 2009.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,036 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 1, 2003. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (851 \text{ days}) + 610 \text{ days} \\ &= 1,036 \text{ days}\end{aligned}$$

Since the regulatory review period began August 31, 1997, after the patent issue date (June 13, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,839,350
Granted	:	June 13, 1989
Original Expiration Date	:	June 13, 2006
Applicant	:	Kunio Atsumi, et al.
Owner of Record	:	Meiji Seika Kaisha, Ltd.

Title : NEW CEPHALOSPORIN COMPOUNDS
AND THE PRODUCTION THEREOF

Classification : 514/202

Product Trade Name : SPECTRACEF® (cefditoren pivoxil)

Term Extended : 1,036 days

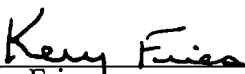
Expiration Date of Extension : April 14, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the Mary C. Till at (571) 272-7755.



Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: SPECTRACEF®
FDA Docket No.: 03E-0036